

Amendments to and Listing of the Claims:

Please cancel claims 1, 5, 6, 10, 11, 13, and 15 -18, without prejudice or disclaimer, and add new claims 19-36, without prejudice or disclaimer, as set forth in the following listing of the claims, which will replace all prior versions, and listings, of claims in the application:

1 – 18. (Cancelled)

19. (New) A non-human transgenic mammal selected from the group consisting of mice, rats, goats, pigs, sheep and cows, whose genome comprises:

(a) an α -lactalbumin (α -LA) promoter; and

(b) a nucleotide sequence linked to the α -LA promoter, the nucleotide sequence encoding a recombinant polypeptide comprising a mammary gland-specific signal peptide and a B-domain deleted human clotting factor VIII (FVIII) polypeptide lacking its innate signal peptide,

wherein the non-human transgenic mammal secretes the B-domain deleted human FVIII polypeptide in milk when the mammal is lactating.

20. (New) The non-human transgenic mammal of claim 19, wherein the mammary gland-specific signal peptide is a bovine α -LA signal peptide of SEQ ID NO:13.

21. (New) The non-human transgenic mammal of claim 20, wherein the bovine α -LA signal peptide is encoded by a DNA sequence of SEQ ID NO: 1.

22. (New) The non-human transgenic mammal of claim 19, wherein the mammary gland-specific signal peptide is a bovine α -S1 casein signal peptide of SEQ ID NO:14.

23. (New) The non-human transgenic mammal of claim 22, wherein the bovine α -S1 casein signal peptide is encoded by a DNA sequence of SEQ ID NO: 2.

24. (New) The non-human transgenic mammal of claim 22, wherein the recombinant polypeptide comprises an amino acid sequence of SEQ ID NO: 15.

25. (New) The non-human transgenic mammal of claim 19, wherein the B-domain deleted human FVIII polypeptide is proteolytically processed intracellularly into a light chain having the A3, C1 and C2 domains and a heavy chain having the A1 and A2 domains, wherein the light chain and heavy chain are operably linked by a junction.

26. (New) The non-human transgenic mammal of claim 19, wherein the α -LA promoter is a 2.0-kb bovine α -LA promoter.

27. (New) The non-human transgenic mammal of claim 19, producing about 50 mg of the B-domain deleted human FVIII polypeptide per litter of milk when the non-human transgenic mammal is lactating.

28. (New) A method for making the non-human transgenic mammal of claim 1, the method comprising:

(a) introducing into an embryo of a mammal a transgene comprising

(i) the α -LA promoter; and

(ii) the nucleotide sequence linked to the α -LA promoter;

(b) implanting the embryo into a female of the same species as the non-human transgenic mammal; and

(c) permitting the embryo to develop into the non-human transgenic mammal of claim 1.

29. (New) The method of claim 28, further comprising confirming the presence of the transgene in the non-human transgenic mammal by polymerase chain reaction (PCR) analysis.

30. (New) The method of claim 28, further comprising confirming the expression of the transgene in the non-human transgenic mammal by reverse transcription PCR analysis.

31. (New) The method of claim 28, further comprising analyzing milk from the non-human transgenic mammal for the B-domain deleted human FVIII polypeptide.

32. (New) Milk collected from the non-human transgenic mammal of claim 19.

33. (New) Milk collected from the non-human transgenic mammal of claim 22.

34. (New) The milk of claim 32 comprising about 50 mg of the B-domain deleted human FVIII polypeptide per litter of the milk.

35. (New) A B-domain deleted human FVIII protein isolated from the milk of a non-human transgenic mammal of claim 19.

36. (New) The B-domain deleted human FVIII protein of claim 35 comprising a light chain having the A3, C1 and C2 domains and a heavy chain having the A1 and A2 domains, wherein the light chain and heavy chain are operably linked by a junction.